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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,586	12/20/2001	Vanessa Chisholm	P1746R1	1705
9157	7590	03/04/2009		
GENENTECH, INC. 1 DNA WAY SOUTH SAN FRANCISCO, CA 94080			EXAMINER SGAGIAS, MAGDALENE K	
			ART UNIT	PAPER NUMBER
			1632	
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			03/04/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/019,586	<b>Applicant(s)</b> CHISHOLM ET AL.	
	<b>Examiner</b> MAGDALENE K. SGAGIAS	<b>Art Unit</b> 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 113-127,130,132-137,140-160,163 and 164 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 113-127,130,132-137,140-151,163 and 164 is/are rejected.
- 7) ☒ Claim(s) 152-160 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's arguments filed 9/11/08 have been fully considered. The amendment has been entered. Claims 1-112, 128-129, 131, 138-139 and 161-162, are canceled.

Claims 113-127, 130, 132-137, 140-160, 163-164 are pending and under consideration.

#### **Improper Multiple Dependent Claims**

Claims 152-160 objection to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must depend from other claims in the alternative only and cannot depend from any other multiple dependent claims is withdrawn in view of the amendment filed 9/11/08.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 151, 163 and 164 rejection under 35 U.S.C. 102(b) as being anticipated by **Tan et al** (US 6,235,967) is withdrawn.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 113-115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lucas

(Nucleic acid Research, 24(9): 1774-1779, 1996 (IDS)); Crowley (US 5,561,053 (IDS) in view of Mosser et al, Biotechnology 22:150-154, 1997 (IDS).

Lucas et al teach a dicistronic expression vector for CHO cells that express both the amplifiable selectable marker DHFR and a cDNA of interest from a single primary transcript via differentially splicing (p 1774-1775). Lucas teaches the dicistronic expression vector combine the advantage of previous dicistronic vectors they link expression of DHFR and the cDNA of interest may bias for active integration events and can accommodate a variety of cDNAs without the need for modification (p 1778, 2<sup>nd</sup> column, last paragraph). Crowley supplements the teachings of Lucas by describing a method of selecting high level producing host cells using a DNA construct containing an amplifiable selectable gene positioned within an intron, and a product gene downstream. Both the amplifiable selectable gene and the product gene are under the control of a single transcriptional regulatory region (see figure 1A). Lucas taken with Crowley differs from the present invention for not teaching a vector with both GFP as a selection marker in the presence of DHFR amplification marker.

However, at the time of the instant invention Mosser et al teach the use of plasmid containing a dicistronic expression cassette encoding GFP and a target gene, in a method of screening and selection of cells expressing inducible genes (p 152-153). Mosser suggests the dicistronic GFP plasmid can be used for identifying clones that stably express a tTA-regulated gene product and also to identify those cells that express a protein of interest following a transient transfection (p 154, 1st column).

Accordingly, in view of the teachings of Mosser it would have been obvious as a design of choice to use the dicistronic vector of Lucas taken with Crowley and introduce the expression cassette encoding GFP into the dicistronic vector of the combined references of Lucas taken with Crowley in order to identify those cells after the DHFR selection as taught by

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Lucas/Crowley. One of ordinary of skill in the art would have been motivated to do such a modification as Mosser suggested the use of GFP as a selection marker.

Supreme Court reaffirmed principles based on its precedent that “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR International Co. v. Teleflex Inc.* (KSR), 550 U.S. at, 82 USPQ2d at 1395. Thus, the claimed invention as a whole, is clearly prima facie obvious in the absence of evidence to the contrary.

### **Obviousness Type Double Patenting Rejections**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 113-127, 130, 132-137, 140-151 and 163-164 **remain** provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-58 of copending Application No. 11/535,038 (hereafter the ‘038 application). Although

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the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite polynucleotides comprising the same components (i.e. amplifiable selectable gene, GFP gene, sequence encoding a desired product with the sequence encoding the desired product operably linked to either the amplifiable selectable gene or to the GFP gene, a promoter, one or two introns, IRES element, etc.), with the components positioned in the same orientation. The claims in the '038 application recite a polynucleotide comprising the aforementioned elements while the instant claims recite a vector comprising the same elements; however, the purpose of the polynucleotides is to express a desired gene of interest, i.e. use as a expression vector. Both sets of claims also recite host cells comprising said polynucleotides and methods of using the polynucleotides to produce the protein of interest.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 113-127, 130, 132-137, 140-151 and 163-164 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-58 of copending Application No. 11/535,003. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite polynucleotides comprising the same components (i.e. amplifiable selectable gene, GFP gene, sequence encoding a desired product with the sequence encoding the desired product operably linked to either the amplifiable selectable gene or to the GFP gene, a promoter, one or two introns, IRES element, etc.), with the components positioned in the same orientation. The claims in the '038 application recite a polynucleotide comprising the aforementioned elements while the instant claims recite a vector comprising the same elements; however, the purpose of the polynucleotides is to express a desired gene of interest, i.e. use as a expression vector.

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Both sets of claims also recite host cells comprising said polynucleotides and methods of using the polynucleotides to produce the protein of interest.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims -127, 130, 132-137, 140-151 and 163-164 **remain** directed to an invention not patentably distinct from claims 1-58 of commonly assigned application 11/535,003. Specifically, the claims are not patentably distinct for the reasons cited in the above obviousness type double patenting rejection.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 11/535,003, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Applicants request to hold the provisional double patenting rejection in abeyance until indication that the instant claims are allowable.

#### **Miscellaneous**

Claim 117, typographical error is withdrawn.

#### ***Allowable Subject Matter***

Claims **152-160** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

**No Claims are allowed.**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,



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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAGDALENE K. SGAGIAS whose telephone number is (571)272-3305.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paras Peter can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1632

/Anne-Marie Falk/  
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